



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-0001]

Pediatric Master Protocols; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA), in collaboration with the University of Maryland Center of Excellence in Regulatory Science and Innovation, is announcing a public workshop titled, "Pediatric Master Protocols". The objective of the workshop is to discuss regulatory and scientific concerns related to pediatric master protocols and clinical trial design considerations for these protocols. In addition, applications of pediatric master protocols to specific pediatric therapeutic areas will be presented.

DATES: The public workshop will be held on September 23, 2016, from 8:30 a.m. to 4:30 p.m.

ADDRESSES: The public workshop will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993-0002. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to

<http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>.

FOR FURTHER INFORMATION CONTACT: Audrey Thomas, Office of Regulatory Science and Innovation, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, rm. 4220, Silver Spring, MD 20993-0002, 301-796-3520, Audrey.Thomas@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: The purpose of this public workshop is to provide an opportunity for relevant stakeholders including: Clinicians and scientists from FDA and other government Agencies, academia, non-profit organizations, and industry to discuss use of pediatric master protocols for development of medical products for children. Specifically, the workshop will present the current status of pediatric protocol development in the United States, considerations for pediatric protocol development internationally, and development of international consortia in this area. Clinical trial design considerations and the preliminary steps needed for development of pediatric master protocols, including the role of in vitro diagnostic tests, will also be discussed. Finally, examples of pediatric master protocol development for medical products with no, partial, and full extrapolation of data from adults to children will be presented. The workshop will include two panel sessions for interaction and discussion among the speakers and attendees.

Agenda: The agenda is available at <http://www.fda.gov/ScienceResearch/SpecialTopics/RegulatoryScience/ucm507079.htm> (FDA has verified the Web site address, but FDA is not responsible for subsequent changes to the Web site after this document publishes in the Federal Register).

Registration: There is a registration fee to attend this public workshop in-person. Seats are limited and registration will be on a first-come, first-served basis. To register, please complete registration online at <http://www.fda.gov/ScienceResearch/SpecialTopics/RegulatoryScience/ucm507079.htm> (FDA

has verified the Web site address, but FDA is not responsible for subsequent changes to the Web site after this document publishes in the Federal Register). There will be no onsite registration.

The costs of registration, to attend in-person, for different categories of attendees are as follows:

Category	Cost
Industry Representative	\$50
Nonprofit Organization and Academic Other Than University of Maryland	\$50
University of Maryland, College Park and Baltimore	\$0
Federal Government	\$0

Streaming Webcast of the Public Workshop: This public workshop will also be Webcast.

There is no registration fee for access to the workshop via the Webcast, but registration is still required. Information regarding registration and access to the Webcast link is available at <http://www.fda.gov/ScienceResearch/SpecialTopics/RegulatoryScience/ucm507079.htm>. If you have never attended a Connect Pro event before, test your connection at https://collaboration.fda.gov/common/help/en/support/meeting_test.htm. To get a quick overview of the Connect Pro program, visit http://www.adobe.com/go/connectpro_overview. (FDA has verified the Web site addresses in this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the Federal Register.)

Accommodations: Attendees are responsible for their own hotel accommodations. If you need special accommodations while at FDA's White Oak Campus due to a disability, please contact Shari Solomon at Shari.Solomon@fda.hhs.gov at least 7 days in advance.

Dated: August 1, 2016.

Leslie Kux,

Associate Commissioner for Policy.

